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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/549,384

11/03/2005

Paul Leonard Greenhaff

SWIN 3306

5375

7812 7590 04/27/2009  
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EXAMINER

KRISHNAN, GANAPATHY

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

04/27/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/549,384	<b>Applicant(s)</b> GREENHAFF ET AL.	
	<b>Examiner</b> Ganapathy Krishnan	<b>Art Unit</b> 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 58-111 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The amendment filed 1/12/2009 has been received, entered and carefully considered. The following information provided in the amendment affects the instant application:

1. Claims 1-57 have been canceled.
2. Claims 58-67, 71-73, 77-84, 88-90, 93-94, 96-103 and 111 have been amended.
3. Remarks drawn to rejections under 35 USC 112, second paragraph, 102 and 103.

Claims 58-111 are pending in the case.

The following rejections have been overcome:

- a) The rejection of claim 63 under 35 USC 112, second paragraph for recitation of the terms, 'active derivative' has been overcome by deletion of the said terms.
- b) The rejection of claim 63 under 35 USC 112, second paragraph for recitation of the term substantially has been overcome by deletion of the said term.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claims 58-111 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is being maintained for reasons of record.

Regarding the rejection of Claim 58 for recitation of the terms, 'carnitine substance', applicants have pointed out to the specification, page 5, which establishes the

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metes and bounds of the said terms. Applicants' arguments are not found to be persuasive. The specification at page 5 recites that carnitine substance comprises one of more of carnitine, a functional equivalent, an active derivative of carnitine or a carnitine analog. The recitations, 'a functional equivalent, an active derivative of carnitine or a carnitine analog' are unclear as to what all are encompassed by these terms. In the absence of clear definitions for what all are included by derivatives, functional equivalents and analogs, the claim is still rendered indefinite.

Regarding the rejection of claim 65 for recitation of the term, 'simple', applicants have traversed the rejection arguing that the term simple would be well understood by those skilled in the art as a group of compounds composed of monosaccharides and disaccharides and have provided supporting references. Even though the references provided define simple carbohydrates and sugars as composed of mono- and disaccharides they also define oligosaccharides as composed of two to ten monosaccharide units. This means a disaccharide is also considered as an oligosaccharide or in other words, a simple carbohydrate also includes an oligosaccharide. It is still not clear if applicants intend only mono- and disaccharides by the said term.

Claims that depend from a rejected base claim that is unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 58-63, 76-80 and 91-92 under 35 U.S.C. 102(b) as being anticipated by Davis et al (EP 0680945; cited in IDS of 11/3/2005) and,

The rejection of Claims 58-65, 74, 76-83, 91 and 93-102 under 35 U.S.C. 102(b) as being anticipated by Pola (WO 01/95915; cited in IDS of 11/3/2005) and,

The rejection of Claims 93-103 under 35 U.S.C. 102(b) as being anticipated by Bohles et al (J. Parenteral and Enteral Nutrition, 1984, 8(1), 9-13; cited in IDS of 11/3/2005) and,

The rejection of Claims 93-103 under 35 U.S.C. 102(b) as being anticipated by Gross et al (Biochim. Biophys. Acta., 1993, 1170(3), 265-274; cited in IDS of 11/3/2005) are all being maintained for reasons of record.

Regarding all of the above rejections Applicants have argued that the key distinction of the claimed subject matter is increase in carnitine retention in skeletal muscle. Applicants' arguments are not found to be persuasive.

The instant claims are all composition claims and what they are used for (intended use) is not given patentable weight. The compositions taught by the prior art above are all seen to comprise the active agents as instantly claimed and are thus seen to anticipate the said claims.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of Claims 63-73, 84-90 and 104-111 under 35 U.S.C. 103(a) as being unpatentable over Davis et al (EP 0680945; cited in IDS of 11/3/2005) in view of Pola (WO 01/95915; cited in IDS of 11/3/2005), Bohles et al (J. Parenteral and Enteral Nutrition, 1984, 8(1), 9-13; cited in IDS of 11/3/2005) and Gross et al (Biochim. Biophys. Acta., 1993, 1170(3), 265-274) is being maintained for reasons of record.

Applicants have traversed the rejection arguing that:

1. The composition of Davis is to stimulate the absorption of carnitine across the intestinal cell wall. This is very different from the instant claims which relate to increasing carnitine retention in skeletal muscle. The uptake of carnitine into skeletal muscle is very different from absorption across the gut wall. Simply increasing the amount of carnitine blood/plasma does not increase carnitine retention in skeletal muscle.

2. Pola teaches a supplement comprising ribose or its phosphorylated analog and a carnitine substance. Ribose does not stimulate insulin production.

3. Bohles discloses administration of carnitine with glucose and the insulin level was reduced.

4. Gross is concerned with carnitine retention in the intestine and not in the skeletal muscle.

Applicants' arguments have been considered but are not found to be persuasive.

Davis teaches compositions comprising carnitine and glycine, which is useful for carnitine absorption (glycine, an amino acid: the agent to increase insulin concentration as in instant claims 58 and 63; pages 5-6; Examples 1-7; limitations of claims 58-63; page 3, lines 16-21). Davis discloses the said composition in the form of an aqueous solution (page 3, lines 48-50).

Gross teaches the uptake and retention of carnitine by rats (abstract, page 266, right column, section entitled-Intestinal levels of carnitine trough page 267). The study also deals with sodium dependent uptake. Gross may not have specifically taught carnitine retention in skeletal muscle. But his teaching still deals with carnitine retention in body tissue.

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Bohles teaches a method increasing carnitine retention by administration of amino acids, glucose (both insulin increasing agents) and L-carnitine to piglets (page 9, abstract and right column, see under Experimental Design). The administration is seen to produce increased energy gain and improvement in nitrogen balance, all of which indicate carnitine retention. Applicants argue that that administration of carnitine with glucose shows a decrease in insulin levels as shown in Table II, period 3 (page 11). According to Bohles (page 9, Experimental Design) during period 3 part of glucose was substituted with fat. During period 1 only glucose was fed. In Table II it can be seen that during period 1, when only glucose was fed insulin level is high. During period 3 the insulin level is low which is to be expected since the amount of glucose intake has been reduced. So, as long as glucose is intake is there it is going to increase the insulin level and also help with the retention of carnitine.

Pola teaches a food/dietary supplement comprising L-carnitine and acyl derivatives of L-carnitine and Ribose (a simple sugar; pages 6-9; pages 11-14; limitations of claims 58-65, 76-83). The composition can be in the form of syrup (page 12, line 3; limitations of claims 74, and 91). Pola teaches that his composition is an effective supplement for prevention of skeletal muscle dysfunction (page 2, second full paragraph) and for energy supply during prolonged physical activity and muscle fatigue. In order for carnitine to perform this function it must be absorbed and retained in the skeletal muscle. Even though ribose may not be taught to increase insulin levels Davis teaches the use of glycine, an amino acid (as instantly claimed) for carnitine absorption and Bohles teaches (and has also demonstrated as explained above) the use of glucose, which increases insulin level. Hence, one of ordinary skill in the art based on the teaching of Bohles and



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Pola would use a composition comprising carnitine and a carbohydrate like glucose that increases insulin level, in a method to increase carnitine retention. This is suggested mainly by the teachings of Boles and Pola. The instant claims are rendered obvious by the prior art.

### ***Conclusion***

Claims 58-111 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ganapathy Krishnan/

Examiner, Art Unit 1623

/Shaojia Anna Jiang/

Supervisory Patent Examiner, Art Unit 1623